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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 14 1998

WARNING LETTER

VIA FACSIMILE
VIA FEDERAL EXPRESS

Kevin Ryan
President
Wesley Jessen Corporation
333 East Howard Avenue
Des Plaines, Illinois 60018

Dear Mr. Ryan:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has reviewed an advertising supplement placed by Wesley Jessen Corporation (Wesley Jessen) in the January 1998 edition of Contact Lens Spectrum. The advertising supplement pertains to, among other lenses, your company's Precision UV™ contact lenses. The contact lenses are devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). The lenses were approved for extended wear as restricted devices within the meaning of section 520(e) of the Act under authority of section 515(d)(1)(B)(ii), P940013, and were also granted marketing clearance for the daily wear use pursuant to Premarket Notification K961299.

In an August 17, 1995, letter to [redacted] company from which Wesley Jessen obtained the ownership of the 510(k) and the PMA, the Center stated that although it recognized that scientific literature suggests that a causal relationship exists between UV radiation and some ocular disorders such as cataracts and cystoid macular edema, the literature provided to the Center as part of the company's supplemental application(s) did not demonstrate that wearing a UV-absorbing contact lens would reduce the incidence of these ocular disorders. Because of this and because there is no evidence that wearing contact lenses offers a clinical benefit, FDA required that all of the labeling and advertising for the lenses include a warning statement informing readers that "UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses. Persons should continue to use their protective UV-absorbing eyewear as directed" and a note stating that "the effectiveness of wearing UV-absorbing contact lenses in preventing or reducing the incidence of ocular disorders associated with exposure to UV light has not been established at this time."

Wesley Jessen has failed to meet these requirements and has promoted its Precision UV™ contact lenses as a substitute for sunglasses. The advertisement reviewed by the agency also implies that wearing Precision UV™ contact lens will protect the eye from exposure

to "invisible rays" that could result in cataracts, macular degeneration and blindness. Although Wesley Jessen included the FDA required statements concerning the wearing of UV-absorbing goggles or eyewear and ocular disorders, the presence of the language does not counteract or balance the overall message of the advertisements, i.e., that Precision UV lenses offer full ocular protection in environments where consumers would expect to wear more traditional forms of UV protection, i.e., sunglasses, UV coated glasses, etc. This is misleading and changes the intended use of the lenses.

Examples include the following statements and representations from the identified supplement:

> Page 4: "Precision UV™ disposables, which block up to 90% of ultraviolet rays, help you avoid the harmful effects of too much sun."
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> Page 6: (a full page advertisement for the company's Precision UV contact lenses). This ad contains numerous inappropriate representations and claims. "HERE COMES THE SUN." The woman lying in the sun without her sunglasses on her face implies that Precision UV™ contact lenses can protect the eyes against potential damage caused by exposure to the sun. Additionally, the woman is lying in a circle representing a contact lens, which implies that the properties of the lens can offer protection from the sun. In large letters, the ad claims that "Precision UV is the first disposable contact lens to block up to 90% of UV rays."
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> Page 6: "Wearing both Precision UV and UV-absorbing sunglasses, you'll enjoy maximum protection from UV light, for good eye health both now and later." Use of this statement implies that even if UV sunglasses are not worn that Precision UV contact lens will offer some protection. This has not been supported.
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> Page 6: "Even moderate long term exposure to these invisible rays can eventually cause cataracts and macular degeneration, and both can lead to blindness" and "Precision UV™ prevents these rays from reaching your cornea, a vital component of the human eye." The text seeks to presents as established fact the relationship between moderate long term exposure to ultraviolet radiation and the medical conditions mentioned. Even though the ad says "can" and not "will," we believe that the references to these conditions are made in order to establish a link between those conditions and the use of your company's lenses for protection from them.

Further, as of March 19, 1998, Wesley Jessen's Internet website at http://www.wesley-jessen.com/clinprop.htm contains inappropriate claims and statements directed at both consumers and practitioners about UV absorbing contact lenses. Among these is an article entitled, "UV Radiation: What You Need To Know Now - Clinical Properties of the Precision UV Lens" authored by Jerome Legerton, O.D., M.S. The article claims, as do your ad and some other pieces on your website, that "Precision UV is the only disposable soft contact lens to offer a UV inhibitor. . ." This statement is misleading and

misbrands you lenses within the meaning of section 502(a) of the act because Precision UV lenses are not the only disposable soft contact lenses in the market place to contain a UV absorber or blocker.

Use of the article, on the World Wide Web (www) quoting the American National Standards Institute as saying that contact lenses claiming UV absorption can allow for 5% transmission of UVB light and 30% of UVA rays, implies that your product blocks 95% of UVB light and 70% of UVA rays. FDA does not believe that the data supplied to the agency clarifies or supports any quantitative transmittance claim for your device. The article also refers to hydrogel lenses as being able to provide protection against peripheral and obliquely incident radiation that sunglasses do not provide, again implying that the lenses are a substitute for sunglasses. The article also refers to benefits gained from Precision UV lenses with regard to artificial light; there have been no data submitted to FDA that would support either a claim that artificial light presents a measurable hazard or a claim that your lenses can protect against such a danger. In addition, your Wesley Jessen consumer website at www.colorcontacts.com contains a reference to the Precision UV lenses as "Sunscreen for your Eyes." The site says, "Now you can give your eyes the same kind of UV protection you give your skin. Precision UV contact lenses absorb an average of 90% of the sun's ultraviolet rays that can cause serious eye damage."

FDA's regulations at 21 CFR 801.4 provide that the term "intended uses" refers to the objective intent of the persons legally responsible for the labeling of the device. That intent may be shown by labeling claims or advertising matter or oral or written statements by such persons or their representatives. Making claims or representations, implied or express, that wearing your company's lenses makes it unnecessary to wear other UV-absorbing eyewear or other protection has changed the intended use for your device. Because your advertisements and other materials have represented that Precision UV contact lenses provide full protection to the eye in environments where protection from UV radiation may be warranted, Precision UV contact lenses are misbranded within the meaning of the following sections of the Act.

The daily wear lenses are misbranded within the meaning of section 502(o) of the Act in that a notice or other information respecting the modification of the intended use of the device was not provided to FDA as required by section 510(k) of the Act. As set forth at 21 CFR 807.81(a)(3)(ii), major changes or modifications to a product's intended use require the submission of premarket notification.

The extended wear lenses are misbranded within the meaning of section 502(o) in that there was a failure to comply with the requirements of section 515 of the Act in that Wesley Jessen failed to file a premarket approval application (PMA) supplement as required by 21 CFR 814.39.

Precision UV contact lenses are adulterated within the meaning of section 501(f)(1)(B) of the Act. The daily wear lenses are adulterated because implying or representing that the lenses are substitutes for sunglasses makes the devices Class III devices within the

meaning of section 513(f) of the Act and the company does not have an approved PMA in effect pursuant to section 515(a) or an approved application for an investigational device exemption under section 520(g). The extended wear lenses are adulterated because they are class III devices without either an approved PMA supplement in effect pursuant to section 515(a) or an approved investigational device exemption under section 520(g) of the Act.

CDRH believes that Wesley Jessen cannot represent that Precision UV™ contact lenses as offering the consumer any specific use or benefit related to the UV blocking quality because the company has not demonstrated any quantifiable or qualitative connection between the blockage of UV radiation by contact lenses and short- or long-term health effects. We recommend that you provide the data necessary to support your claim of 90% blockage of UV rays and then confine your marketing to quantitative claims that accurately reflect those transmittance data. Implying any health benefit negates, as discussed above, the required note and warning statements.

This letter is not intended to be an all-inclusive list of deficiencies associated with the Precision UV lenses. It is your responsibility to ensure adherence to each requirement of the Act and the Federal regulations. The specific violations discussed in this letter may represent practices used in other promotional or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to ensure compliance with applicable requirements.

You should take prompt action to correct these violations. Failure to correct these deviations may result in FDA's initiating regulatory action without further notice. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product and assessing civil money penalties.

Please notify this office in writing within 15 working days of your receipt of this letter of the specific steps you have taken to correct the cited violations. Your response should include steps being taken to address misleading information currently in the marketplace as a result of your print advertising campaigns and any other campaigns, e.g., radio or television, that you may be conducting. Your corrective actions should address violations that may be posed by advertising materials now pending publication. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Send your response to Deborah Wolf, Regulatory Counsel, Promotion and Advertising Policy Staff, Office of Compliance (HFZ-302), Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.A copy of this letter is being sent to FDA's Chicago District Office. Please send a copy of your response to the District Director, Food and Drug Administration (HFR-MW140), 300 S. Riverside Plaza, 5th Floor, Suite 550 South, Chicago, Illinois 60606.

Sincerely yours,

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Lillian Gill
Director
Office of Compliance
Center for Devices and
Radiological Health